HFEA Licence Committee Meeting

10 July 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 8

Centre 0208 (South East Fertility Clinic) – Incident Report

Members of the Committee: Andy Greenfield (lay) (Chair) David Archard (lay) Debbie Barber (professional) Jane Dibblin (lay)	Legal Adviser: Tom Rider, Fieldfisher Committee Secretary: Lauren Crawford

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- HFEA's root cause analysis
- Centre's root cause analysis
- Copy of letter sent to patients affected by the incident
- Executive Licensing Panel minutes for last 3 years:
- Renewal inspection minutes (7/02/2014)
- Interim inspection minutes (8/02/2013)
- Interim inspection minutes (21/01/2011)
- Email from Anne Sprintham, SEFC, to HFEA (09/07/2014)

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012

- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted that South East Fertility Clinic is a privately run centre and provides a wide range of fertility treatments. The centre carries out approximately 600 cycles of licensed treatment a year. The centre was first established in 2004 and a licence renewal inspection took place on 19 & 20 November 2013. At the time of inspection no critical non-compliances, no major non-compliances and 7 other non-compliances were noted. The Executive Licencing Panel (ELP) granted the centre a four-year licence with no additional conditions.

2. The Person Responsible (PR) is also the Clinical Director for the centre and has been in post since 2004. This is the first time an incident of this nature has been reported by the centre.

Discussion

3. The Committee noted that on 5 February 2014 seven patients had egg collection. Good fertilisation was observed on 6 February 2014. The embryos were transferred to culture dishes that day. Some cytoplasmic shrinkage was noted in some embryos at the time. Fresh media was made up but the embryos were not transferred into this until the following day.

4. The Committee noted that no cleavage was observed in the embryos of two patients on 7 February 2014 but cleavage occurred on 8 February 2014. These two patients did not have embryo transfer at this stage and embryos remained in culture in an attempt to culture to the blastocyst stage.

5. The Committee noted that two further patients had normal cleavage on 7 February 2014 and had embryo transfer on 8 February 2014. The remaining three patients' embryos had achieved what was considered a slow cleavage rate on 7 February 2014. One patient had an embryo transfer on 8 February 2014 and one had a blastocyst transfer on 10 February 2014.

6. The Committee noted that no embryos were cryopreserved. The four patients who underwent embryo transfers have all reported negative pregnancy tests.

7. The Committee noted that centre carried out a full investigation. As all temperature and gas levels within the incubator were within normal limits the investigation focused on the following:

- The patient mix: this was complex meaning that it may have simply been a matter of chance that the cohort of patients all failed to achieve usual rates of embryo cleavage and pregnancy.
- The possibility that there was a problem with the osmolarity (concentration) of the culture medium used on 6 February which led to the poor cleavage rate and failure of the embryos to develop. This scenario could explain the observation of cytoplasmic shrinkage.
- The possibility that human serum albumin (HSA) was not added to the media. It is usually added to the media when the dishes for the day 1 changeover are prepared. There is no way of proving whether this was a factor, but if it were to be the case it could also explain the shrinkage observation.
- It is possible that the G1-G3 dishes were prepared incorrectly permitting evaporation of media at the time of preparation, which could explain the unusual appearance (swirling) of the media in the dishes the following day. This could have been caused by the preparation of the medium on the heated stage and/or untimely addition of the oil overlay or insufficient amounts of media.

8. The Committee noted that the PR immediately informed the HFEA as soon as he was made aware of the situation. The PR also arranged for two external assessors to review the centre's investigation report along with the centre's processes to ensure all the issues had been covered and thoroughly explored.

9. The Committee noted that the centre tried to recreate the different scenarios to ascertain the one most likely to have caused this incident, however, the investigation proved inconclusive. One of the external assessors surmised that it is quite likely that the oil overlay was missed or insufficient and that water was lost from the culture drops causing a change in osmolality and viscosity.

10. The Committee noted that all patients were fully informed and offered another cycle of treatment free of charge.

11. The Committee noted the lessons learned by both the centre and the Executive that ‘All members of staff are responsible for the safety of the gametes and embryos in their charge. Concerns should be acted on promptly and appropriately. If any member of staff is concerned that the appropriate action has not been taken this should be escalated to a more senior member of staff immediately. Further to this the senior member of staff must act on any concerns brought to their attention’.

12. The Committee noted that there are no further corrective actions to be taken in regards to this incident.

Decision

13. The Committee was satisfied that the centre responded to the incident and the necessary corrective actions have been taken by both the centre and the Executive in this case, and closed this incident.

Signed: Date: 23/07/2014

Andy Greenfield (Chair)

Incident Investigation Report

Centre no 0208 – incident number IN03714

Since October 2009 the HFEA has published A grade incident reports and the associated Licence Committee minutes on our website.

Background of the licence and the licencing history

South East Fertility Clinic is a privately run unit and provides a wide range of fertility treatments. The centre carries out approximately 600 cycles of licensed treatment a year.

The centre was first established in 2004 and a licence renewal inspection took place on 19 & 20 November 2013. At the time of inspection no critical non-compliances, no major non-compliances and 7 "other" non-compliances were noted. The Executive Licencing Panel (ELP) granted the centre a four year licence with no additional conditions.

The Person Responsible (PR) is also the Clinical Director for the centre and has been in post since 2004.

This is the first time an incident of this nature has been reported by the centre.

Summary Incident Description & Consequences

On the 5 February 2014 seven patients had egg collection. Good fertilisation was observed on 6 February 2014. The embryos were transferred to culture dishes that day. Some cytoplasmic shrinkage was noted in some embryos at the time. Fresh media was made up but the embryos were not transferred into this until the following day.

No cleavage was observed in the embryos of two patients on 7 February 2014 but cleavage occurred on 8 February 2014. These two patients did not have embryo transfer at this stage and embryos remained in culture in an attempt to culture to the blastocyst stage[1].

Two further patients had normal cleavage on 7 February 2014 and had embryo transfer on 8 February 2014.

The remaining three patients had achieved what was considered a slow cleavage rate on 7 February 2014. One had an embryo transfer on 8 February 2014 and one had a blastocyst transfer on 10 February 2014.

No embryos were cryopreserved. The four patients who underwent embryo transfers have all reported negative pregnancy tests.

The centre carried out a full investigation. As all temperature and gas levels within the incubator were within normal limits the investigation focused on the following.

1. The patient mix: this was complex meaning that it may have simply been a matter of

[1] One patient was 43 years of age with a low AMH

chance that the cohort of patients all failed to achieve usual rates of embryo cleavage and pregnancy.

2. The possibility that there was a problem with the osmolarity (concentration) of the culture medium used on 6 February which led to the poor cleavage rate and failure of the embryos to develop. This scenario could explain the observation of cytoplasmic shrinkage.
3. The possibility that human serum albumin (HSA) was not added to the media. It is usually added to the media when the dishes for the day 1 changeover are prepared. There is no way of proving whether this was a factor, but if it were to be the case it could also explain the shrinkage observation.
4. It is possible that the G1-G3 dishes were prepared incorrectly permitting evaporation of media at the time of preparation which could explain the unusual appearance (swirling) of the media in the dishes the following day. This could have been caused by the preparation of the medium on the heated stage and/or untimely addition of the oil overlay or insufficient amounts of media.

The centre tried to recreate the different scenarios[2] to ascertain the one most likely to have caused this incident however the investigation proved inconclusive. One of the external assessors surmised that it is quite likely that the oil overlay was missed or insufficient and that water was lost from the culture drops causing a change in osmolality and viscosity.

Incident type:	Laboratory process
Specialty:	Gamete and embryo culture
Effect on patient:	Potential suboptimal conditions for embryo development for seven patients[3].
Severity level:	Grade A

Scope and Level of Investigation
HFEA Root Cause Analysis
Discussions with senior staff
Discussions with staff on duty at the time of the incident
Centre no 0208 investigation report

Involvement and support of Patient and Relatives
All patients were fully informed and offered another cycle of treatment free of charge.

Notable Practice
As soon as the PR was made aware of the situation he immediately informed the HFEA executive.
The PR arranged for two external assessors to review the centre's investigation report along with the centre's processes to ensure all the issues had been covered and thoroughly explored.

Contributory Factors
Senior embryologist[4] did not act upon the concerns raised by the junior member of staff.
Staff were not aware that it would be safer to leave injected eggs in original dishes rather than carrying on moving them into a potentially unsafe environment.

Root Causes

[2] The original dishes were discarded instead of being quarantined and examined further.
[3] Resulting in three patients having their cycles cancelled and negative pregnancy tests for the other 4 patients.
[4] This member of staff is no longer works at the clinic.

Failure to adhere to laboratory protocol[5]. Poor decision making on the day by the senior embryologist.			
Lessons Learned All members of staff are responsible for the safety of the gametes and embryos in their charge. Concerns should be acted on promptly and appropriately. If any member of staff is concerned that the appropriate action has not been taken this should be escalated to a more senior member of staff immediately. Further to this the senior member of staff must act on any concerns brought to their attention.			
Recommendations There are no further recommendations relating to this adverse event.			
Action Plan - All corrective actions have been taken.			
Implementation, monitoring and evaluation arrangements All actions have been implemented.			
Author	Paula Nolan (Clinical Governance Lead/Inspector)	**Date**	14 May 2014

[5] "*if at any stage of placing oocytes/embryos into a dish any viscosity is observed stop the procedure immediately and work out which well/dishes are safe to use".*

1. Details of Incident reported:

Wednesday 5th February 2014:
Seven patients had egg collection. There were six cases of ICSI and one of IVF.

Thursday 6th February 2014:
Good fertilisation was observed in all 7 cases. The embryos were transferred to Day 1 culture dishes. Some cytoplasmic shrinkage was noted in the embryos of one patient whose embryos were in the GO dish, the significance of which was unclear. Concern was noted by the trainee embryologist regarding the quality of the media in the day 1 dishes and as a result, fresh media and dishes were made up and left to equilibrate overnight. The embryos were transferred into this second batch of media and dishes on the following day - Friday 7th February 2014.

No cleavage was observed in two patients but cleavage occurred late on Friday 7th February 2014. Embryo culture continued in an attempt to reach the blastocyst stage but these two patients did not have embryo transfer. One patient was 41 years of age with severe endometriosis and just six eggs.
Two patients had normal cleavage and had embryo transfer on Saturday 8th February 2014
Three patients had a low cleavage rate. One had an embryo transfer on Saturday 8th February 2014 and one had a blastocyst transfer on Monday 10th February 2014.
No embryos were cryopreserved for any patient.
The embryo development observed for these cases was lower than expected hence the incident report.
3 patients had their cycles cancelled as no embryos were suitable for transfer.

Friday 21st February 2014: 4 patients reported negative pregnancy tests.

Consideration was given to possible causes. All temperature and gas levels were within normal limits during the period of culture. These are continuously monitored and logged:

1. The patient mix was complex and it may have simply been a matter of 'bad luck' due to the nature of the patients.
2. There is the possibility that there was a problem with the osmolality of the pre-prepared Global culture media which led to the poor cleavage rate and failure of the embryos to develop. This would explain the above findings.
3. It is possible that Human Serum Albumin (HSA) was not added to the Global media. It is usually added to the media when the dishes for the day 1 changeover are prepared. There is no way of proving this, but if it were to be the case it could also explain the above findings.
4. It is possible that the G1-G3 dishes were prepared incorrectly permitting evaporation of media at the time of preparation which could explain unusual appearance (swirling) of the media in the dishes the following day. This could have been preparation on the heated stage, untimely addition of the oil overlay or insufficient amounts of media.

2. Statements requested and received from:

Senior Embryologist 1 [redacted] Junior Embryologist 1 [redacted]
Junior Embryologist 2 [redacted] Senior Embryologist 2 [redacted]

Laboratory Manager: interview on return from sick leave on Mon. 10th March 2014 as not at work when incident occurred.

3. Patients:

Patients were informed by embryologists on Day 1 or day 2 that the progress of embryo development was not as expected and that SEFC would review the procedures. All patients contacted by a fertility nurse following discussion by clinical staff at multi-disciplinary meeting on Wednesday 26th February 2014.
Couples have all had a follow up consultation with a clinician. They have all been offered and accepted a complimentary cycle to be commenced when appropriate for their clinical and personal circumstances.

4. Escalation and Information to external bodies:

Incident reported to the HFEA on Tuesday 11th February 2014
Incident reported to Kent and Medway Commissioning Support Unit on Monday 10th March 2014.

5. Timeline

Day -2	Monday 3rd Feb	G0 media made up from Global media and protein supplement.
Day -2	Monday 3rd Feb	G0 media stored in fridge for 24 hours as per manufacture's instructions
Day -1	Tuesday 4th Feb	G0 dishes prepared
Day -1	Tuesday 4th Feb	G1-3 media prepared in 50 ml flask using 9 parts Global media and 1 part Human Serum Albumin (10%). Prepared media stored in refrigerator. Junior Embryologist 2
Day 0	Wed 5th Feb	G1-G3 dishes prepared using media prepared the day before and taken from the fridge. Dishes put into incubator for use the following day. Senior Embryologist 2 Coincidentally the same senior embryologist was required to prepare G3-G5 dish for another patient (xx) who had an egg collect on Monday 3rd Feb. She prepared another batch of media (Global +HSA), prepared the dishes for G3-G5 to receive the embryos on the following day. On review patient reported a positive pregnancy test.
Day 0	Wed 5th Feb	Egg collections for 7 patients
Day 0	Wed 5th Feb	ICSI x 6 and IVF x 1 completed and placed in G0 dishes overnight.
Day 1	Thurs 6th Feb	Fertilisation check and patient calls
	Concerns raised by junior embryologist 1 to senior embryologist 1 re the observation that 'the majority of droplets in the dishes had different viscosity'. Junior embryologist 1 reported that all the G1-G3 dishes were of concern. Embryos moved into G1-G3 dishes. Senior embryologist 1 reviewed one or possibly more dishes (statements contradictory) and advised junior embryologist 1 to continue to transfer the embryos to the 'suspect' dishes.	

	During fertilisation check on Day-1 (06-02-14), it was noticed that (patient) G0 dish seemed to have oil and media expelled out of the 4-wells into the central well and edges. The injected eggs were situated in wells which hardly had any media. Eggs were almost sticking to the bottom of the dish. Eggs appeared very granular with cytoplasmic shrinkage and as soon as transferred to the G-I dish showed some expansion. The significance of these observations is unknown. Patient achieved a total of 13/16 fertilised oocytes.	
	New G1-G3 media prepared and stored in the fridge by trainee embryologist (xx) for the 24 hour period which the embryologists understood was required by manufacturers. SEFC protocols state that dishes should be equilibrated for no less than 3 hours The team had previously been advised by Global that24 hour storage prior to use is not a pre-requisite of use.	
Day 2	Fri 7th Feb AM	Day 2 checks – all the embryos were moved out of the original G1-G3 dishes and put into the new dishes immediately after the checks had been made.
	Fri 7th Feb	Day 2 phone calls - Embryologist phoned 6 patients with suspected slow or no cleavage
	Fri 7th Feb PM	Day 2 checks - some cleavage noted and pronuclei had disappeared.
	Fri 7th Feb	Senior Embryologist () raised with Consultant/PR
Day 3	Sat 8th Feb	3 patient cycles cancelled due to poor development of fertilised embryos. Day 3 checks and patient calls. 3 patients had embryo transfers of Day 3 embryos
Day 5	Mon. 10th Feb.	1 patient had Day 5 Blastocyst transfer
Day 16	Friday 21st Feb.	4 patients reported negative pregnancy tests.
Day 21	Wed. 26th Feb	Patients discussed at multi-disciplinary review clinical meeting and advised to seek appointment with consultant as normal practice for failed or cancelled cycle.
	Mon. 3rd March onwards	Patient/couples attended SEFC for consultant appointment.

6. Investigation Report

Supposition 1:

The patient mix was complex and the poor outcomes may have simply been a matter of 'bad luck' due to the nature of the patients' clinical histories

Conclusion: The patient mix and past history including previous ART cycles was reviewed and although complex, there was no indication that all of the cycles would fail to either proceed to embryo transfer or to a negative pregnancy test. The expected rate of cleavage failed to materialise.

Supposition 2:

There is the possibility that there was a problem with the osmolality of the prepared culture media which led to the poor cleavage rate and failure of the embryos to develop.

Conclusion: The manufacturers of the base medium were asked to report on concerns about the batch of medium. None were reported.

Supposition 3:

The cleavage media was incorrectly made up possibly omitting the addition of the Human Serum Albumin.

Conclusion: It is not possible to substantiate this supposition as the evidence (media and dishes) were disposed of on the authority of senior embryologist 1 to avoid any confusion with other equipment or media, before any post-incident analysis could take place. It is the view of the senior embryologist 1 that it would have been visibly obvious to the members of the team if this had happened. This was not substantiated by the laboratory manager in attempts to replicate the event.

Supposition 4:

That the G1-G3 dishes were incorrectly prepared prior to being used.

Conclusion: Consideration was given to the way in which senior embryologist 2 prepared the G1-G3 dishes on the day of egg collection. She reported no change from her usual practice. She has 16 years of experience and reported no concerns about the methods used to prepare these dishes. She reported that the dishes were prepared one by one, oil used to cover wells before the next dish was started and all the dishes were checked before she left in the evening. No concerns were raised about this stage. It was also noted that in the same session, the same embryologist prepared a new batch of media for a G3-G5 dish for patient xx and prepared the dish. Although the drops used in the preparation of G3-G5 dishes are bigger than those for G1-G3 dishes, the patient is pregnant concluding that there were no problems with the embryologist's method of preparation.

It is not possible to prove or disprove that the preparation may have been at fault as the evidence was disposed of before the post-incident investigation was commenced. It is the opinion of both junior embryologists that the dishes were prepared incorrectly on a heated stage resulting in evaporation of the medium. An additional statement by junior embryologist 2 to substantiate this supposition has been requested (22nd April 2014)

The Root Cause of the incident is that the embryos were transferred into dishes which the embryologists (junior embryologists 1 and 2, senior embryologist 1) considered to contain sub-optimal media.

The investigation concludes that it is not possible to establish whether the preparation of the media or the dish preparation were the primary cause of the sub-optimal media.

However on recognising that there were concerns with the quality of the media and/or the prepared dishes, junior embryologist 1 and senior embryologist 1 failed to prevent further harm or to take action to reverse any harm already caused.
In detail:

6.1 junior embryologist 1 failed to recognise the consequences of transferring fertilised eggs into media which she suspected was sub-optimal

6.2 junior embryologist 1 failed to understand and recognise that the day 1 fertilised eggs could safely remain in the day 0 dishes until another safe environment was established

6.3 Both junior embryologists 1 and 2 and senior embryologist 1 failed to recognise the similarity with a near miss which occurred in autumn 2013 when dishes were deemed unusable by the Laboratory Manager. The change in working practices at that time clearly states that

> *'If at any stage of placing oocytes/embryos into a dish any viscosity is observed stop the procedure immediately and work out which wells/dishes are safe to use'*

Had they taken appropriate action as dictated by the instructions above, changeovers would have stopped, the embryos left in G0 dishes until more detailed analysis and senior opinion had been sought.

6.4 senior embryologist 1 failed to provide leadership and supervision to junior staff in that she:

6.4.1 failed to understand and recognise that the day 1 fertilised eggs could safely remain in the day 0 dishes until another safe environment was established

6.4.2 failed to stop the process of changing over the fertilised eggs into media which was thought to be sub-optimal and therefore unsafe to use

6.4.3 failed to act as the senior embryologist on the day and take over responsibility for the changeover of the fertilised eggs from junior embryologist 1 and therefore assuming responsibility for the safe keeping of the embryos

6.4.4 failed to recognise the significance of retaining the flask and dishes to assist in the investigation – all available evidence was disposed of before it could be reviewed

6.4.5 failed to follow the agreed procedure (Standard Operating Procedure for Failed Fertilisation, abnormal fertilisation or failure to reach embryo transfer, after IVF/ICSI) as agreed by the Company.

6.4.6 failed to interrogate the systems available to identify equipment malfunction or failure which may have caused the deterioration of the medium.

7. Contributory Factors:

7.1 Care or Service Delivery

- Investigation did not reveal any issues with Care or Service Delivery.

7.2 Guidelines, Policies and Procedures

- There was no existing protocol defining the procedure for preparation and storage of media requiring the mixing of Global media and Human Serum Albumin (HSA) (protein).
- There was no comprehensive protocol for the preparation of Nunc 4-well dishes containing cleavage media which refers to the use of pre-prepared media and the recommended sequence of preparation

7.3 Procedural or Task Design

- A similar near miss had occurred in autumn 2013 when the Laboratory Manager noticed that dishes had sub-optimal media for the changeover of fertilised eggs. The event was discussed with the laboratory staff and working practices revised. Clear instructions were issued to and discussed with all laboratory staff as to the correct actions should such an event occur again.
- Cleavage Media is prepared by a member of the embryology staff and stored in the refrigerator for 24 hours prior to use
- Dishes are prepared with media from the refrigerator by a different member of the embryology staff to the one who may have prepared the flask of media.

7.4 Competence

- During the investigation the junior embryologists reported that they were not aware that the prepared media could be used within 4 hours of preparation and did not need to be equilibrated overnight or for 24 hours before being used. SEFC is unable to verify whether the senior embryologist 1 was aware of this as she no longer works at the clinic.
- Inexperience – there are no ongoing or outstanding concerns about the clinical practices of the junior embryologist 1 and 2.
- Supervision – senior embryologist 1 had responsibility on the day for the supervision of the junior embryologists. This was found to be inadequate
- Leadership was ineffective with clinically inappropriate and untimely decision making

8. Recommendations:

8.1 To attempt to replicate some of the events observed in the incident:

8.1.1 Knocking or jolting of dishes resulting in disturbance of media and embryos – tipping and rolling dishes to angles in excess of 90° to the horizontal and tipping completely upside down failed to spill all of the media and embryos out of the wells and into the central area of the dish. The degree of disturbance observed could not be replicated. the junior embryologists are to conduct an experiment to try and replicate what was seen in the G0 dish in which the media appeared to have been spilled out of the wells leaving embryos almost stuck to the bottom of the wells.

8.1.2 Identification (by eye) of the lack of HSA in media. The laboratory manager prepared dishes using media without HSA added and attempted to identify whether the drops/wells looked unusual to the naked eye. It is her opinion that it is not possible to identify the lack of HSA using observations alone.

8.1.3 that the junior embryologists conduct an experiment to try to replicate the preparation of the dishes on the heated stage resulting in changes in viscosity on the media and changes in the wells of the dishes. Particular care will be taken to replicate the conditions of the original set up including time of day etc

8.2 To arrange a laboratory staff meeting to discuss investigation report – to have the opportunity to comment on the recommendations and root causes

8.3 To write an agreed protocol for preparation and storage of cleavage media.

8.4 To write an enhanced protocol for preparation of dishes using prepared media.

8.5 To ensure that Competencies linked to these protocols are written and completed

8.6 To recommend that all laboratory staff are trained to download and interpret the incubator monitoring (temperature and pH). The external monitoring system, in situ since April 2013, records the temperature and pH measurements at 15 minute intervals 24 hours per day. The records are retained indefinitely.

8.7 All patients/ couples should be offered a complimentary IVF/ICSI cycle by the Consultant Gynaecologist at an outpatient consultation as soon as is practicable. (All couples have been seen).

8.8 An anonymised summary report should be shared with all SEFC staff.

8.9 The laboratory staff will present a case summary to all SEFC staff for discussion and clarification

8.10 The investigation report should to be sent to:

8.10.1 HFEA

8.10.2 Kent and Medway Commissioning Support Unit

8.11 That advice is sought from the HFEA regarding reporting senior embryologist 1 to the Health Care Professions Council (HCPC).

8.12 That an external Laboratory Manager and Senior Embryologist reviews this report to confirm it has been conducted thoroughly and fairly and that the conclusions drawn are valid. (This has been done and agreed).

9 Action Plan and Monitoring

The recommendations listed above will form part of the Incident Action plan and will be monitored by:

Monthly Managers Meetings

Quarterly Quality and Governance Meetings

Audit of compliance with laboratory protocols for the preparation of media and dishes including storage and transfer procedures

Action	Timescale	Responsible Officer
Junior Embryologists 1 and 2 to conduct experiments in an attempt to replicate the conditions in which the dishes may have been prepared and to attempt to dislodge media and embryos in a G0 dishes and to report their findings to Person Responsible	10th May 2014	Laboratory Manager
Senior embryologist 1 is no longer an employee of SEFC. She has been sent a copy of the draft report and given the opportunity to comment. She has had a telephone conversation with the laboratory manager and notes documented. In addition she has emailed her comments to SEFC for the record.	Report sent for comment on Tuesday 18th March. Comments received in email. Notes from telephone conversation documented.	Quality Manager Lead Consultant (Quality Lead) Laboratory Manager
Laboratory staff meeting to discuss investigation report – to have the opportunity to comment on the recommendations and root causes	Wednesday 12th March 2014 Completed	Laboratory Manager Quality Manager Person Responsible
Laboratory procedures have been changed with immediate effect to ensure that one embryologist is responsible for the preparation of media and dishes. **Protocol for the addition of protein supplement to culture medium LAB 199 -** includes additional witnessing stage to ensure that protein is observed to be added and also a cross-check of the media bottles with the flask they are going into	Completed	Laboratory Manager

Protocol for Laboratory Set-up LAB 169 - New section describing exactly how to dispense media into dishes - air-flow, temperature, timings etc **Protocol for Fertilisation Check and Embryo Sub-Culture LAB78 -** Trouble shooting section added. How to proceed if there are observed problems with the media in the change-over dishes. **Competency for Preparation of Dishes for Embryo Culture and Assessment of Dishes Prior to Use HRLC8 -** Assesses embryologists understanding of culture system in use at SEFC, understanding of how inappropriate culture conditions can harm embryos, how to handle the media correctly and what to do if things go wrong.		
Laboratory staff to ensure they can read the daily checks of the temperature and pH in the incubators.	Complete / Octax Log & Guard	Laboratory Manager
All patients/ couples to be offered a complimentary ICF/ICSI cycle.	Completed	Administration Manager
Anonymised summary report to be shared with all SEFC staff following HFEA visit to SEFC	30th April 2014 Pending HFEA feedback report	Quality Manager
Investigation report to be sent to: HFEA – pending feedback from HFEA visit to SEFC on 16th April and receipt of HFEA report to SEFC Kent and Medway Commissioning Support Unit Consideration of further referral to professional bodies	Completed 30th April 2014	Quality Manager
SEFC will submit a copy of the draft report to an external embryology expert for review of the investigation • appropriateness • completeness • scope • conclusions and • recommendations Agreement in principle to be sought from HFEA	Completed - 28th March 2014 Completed – 26th March 2014	PR Quality Manager
Person Responsible to write to 7 couples to inform them of investigation, findings and HFEA feedback	TBC – pending HFEA feedback report from Licensing Committee	Person Responsible
Person Responsible to write to Senior Embryologist 1 with findings of SEFC report and HFEA final report with recommendations. Advice to be shared re sharing final report with professional body – HPCP.	TBC – pending HFEA feedback report from Licensing Committee	Person Responsible
Junior Embryologists 1 and 2 and Senior Embryologist 2 to present the case study to SEFC staff in an open discussion re root causes	31st May 2014	Laboratory Manager

and subsequent actions.		